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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/674,653	09/30/2003	Marc E. Feinberg	ETH5092	4786
27777	7590	04/27/2007		
PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003			EXAMINER POUS, NATALIE R	
			ART UNIT 3731	PAPER NUMBER
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		04/27/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/674,653

Applicant(s)

FEINBERG, MARC E.

Examiner

Natalie Pous

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 April 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,5,6,8,10,12,14,16,18 and 21-31 is/are pending in the application.
- 4a) Of the above claim(s) 21 is/are withdrawn from consideration. *ATW*
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,5,6,8,10,12,14,16,18 and 21-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1,5,6,8,10,12,14,16,18 and 21-31 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 1/16/04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/5/07 has been entered.

Response to Arguments

Applicant's arguments with respect to claims 1,5,6,8,10,12,14,16 and 18-21 have been considered but are moot in view of the new ground(s) of rejection based on amendments to the claims. However, for the purpose of clarity, examiner will explain her position with respect to Benetti. Applicant argues that Benetti fails to teach an adhesive pad. Examiner respectfully disagrees. The claim language does not define any structural limitations limiting the adhesive pad, and it is noted that according to Merriam Webster, an adhesive is defined as tending to remain in association. The pad (4) of Benetti works to allow the device to remain in association with the tissue, and thus is an adhesive. Therefore, examiner sustains that Benetti teaches an adhesive pad.

Applicant's arguments with respect to the 35 USC 103(a) rejections have been considered but are moot in view of the new ground(s) of rejection based on amendments to the claims.

Applicant's arguments with respect to the combination Huttner and Hasson have been considered but are moot in view of the new ground(s) of rejection based on amendments to the claims.

Election/Restrictions

Newly Amended claim 21 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1,5,6,8,10,12,14,16,18 and 22-30, drawn to apparatus, classified in class 606, subclass 150.
- II. Claim 21, drawn to method of use, classified in class 128, subclass 898.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case (1), the method as described by newly amended claim 21, includes the limitation wherein providing the tissue approximation device includes connecting an adhesive pad to an end of each elongate arm and adjusting a position of each pad relative to the skin surface. This limitation not required by the original method claim distinguishes this method from the

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originally presented apparatus; in that the apparatus may be manufactured with the adhesive pad connected to the elongate arm, and thus may be used in a method not requiring that step.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art due to their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 21 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 5, 6, 10, 14, 16, 22 and 27-30 rejected under 35 U.S.C. 102(b) as being anticipated by Taylor et al. (US 6394951).

Regarding Claim 1, Taylor teaches a tissue approximation device comprising two elongate arms (3), an attachment means (144) to secure the elongate arms to each

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other at one or more locations, adhesive pads (4, Column 14, proximate lines 1-37) movably connected (18, 19) on at least a portion of the elongate arms to anchor the tissue approximation device to the tissue (fig. 321a), and a locking means (181) to lock the elongate arms in place relative to each other, wherein (i) the adhesive pads are spaced apart from the one or more locations of the attachment means (144) in the direction of the elongate arms, and (ii) the tissue approximation device has an open (fig. 31b) and a closed position (fig. 31a), and when in the closed position, the adhesive pads are parallel and non-contiguous to each other (fig. 31a).

Regarding Claim 5, Benetti teaches the tissue approximation device of claim 1, wherein the elongate arms (3) form a pair of forceps, the attachment means (144) is a yoke on the forceps, and the locking means (151) is a ratchet mechanism on the forceps.

Regarding Claim 6, Taylor teaches the tissue approximation device of claim 5, wherein the distance between the elongate arms is adjustable by means of a ratchet mechanism (151).

Regarding Claim 10, Taylor teaches the tissue approximation device of claim 5, wherein the adhesive pad having first adhering surface (4) and a second surface having a ball (18) that communicates with a socket (19) on the distal end of the arm.

Regarding Claim 14, Taylor teaches the tissue approximation device of claim 5, wherein the adhesive pad having first adhering surface (4) and a second surface having a male protruding mechanism (18) that communicates with a female receiving mechanism (19) on the distal end of each of the elongate arms (3).

Regarding Claim 16, Taylor teaches the tissue approximation device of claim 5, wherein the distal end of the elongate arms has a passageway (19) therein such that the adhesive pad (17) communicates with said passageway (19).

Regarding Claim 22, Taylor teaches a tissue approximation device capable of application to a skin surface adjacent to a wound comprising: a pair of arms (3), each arm having a longitudinal axis and opposed ends, wherein one end includes a handle (fig. 31a) and the other end includes a tong (1) with a connector (19); and an attachment mechanism coupled to each arm (144) such that the distance between each tong is selectively variable; an adhesive pad (4) removably coupled to the connector of each tong (18) wherein each adhesive pad has an adhesive surface (4) that extends in a plane generally parallel to the longitudinal axis of the respective tong (fig. 2), the adhesive surface having a high shear resistance, and wherein the connectors support the adhesive pads to be positionable in a common plane on opposed sides of a wound; and a locking mechanism (151) coupled to each arm to selectively lock the pair of arms in a fixed position relative to each other.

Regarding Claim 27, Taylor teaches the device of claim 22, wherein the arms are connected in a scissors configuration (fig. 31a)

Regarding Claim 28, Taylor teaches the device of claim 22, wherein the adhesive pad (4) includes serrations

Regarding Claim 29, Taylor teaches the device of claim 22, wherein the locking mechanism (151) includes a ratchet.

Regarding Claim 30, Taylor teaches the device of claim 22, wherein the arms (3) are made of resilient material (Column 12, proximate lines 50-60, it is noted that the present application only describes that the arms may be made of either plastic or stainless steel, as taught by Taylor)

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 12, 18, 23 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Taylor in view of Fogarty (US 4821719). Taylor teaches all limitations of preceding dependent claims 1, 5 and 22, but fails to teach a pivoting connector wherein the adhesive pad has a first surface and a second surface having a female receiving mechanism that communicates with a male protrusion on the distal

end of each of the elongate arms, or wherein the adhesive pad has a passageway therein, such that the distal end of each of the elongate arms is within said passageway.

Fogarty teaches a device for tissue approximation including a pivoting connector (it is noted that since adhesive pad 30a is capable of sliding onto tong 52, and is cylindrical in shape, it is inherently capable of pivoting about the longitudinal axis of the tong 52) wherein the adhesive pad has a first surface (30a) and a second surface (55) having a female receiving mechanism that communicates with a male protrusion (52) on the distal end of each of the elongate arms (fig. 5), or wherein the adhesive pad has a passageway therein (55), such that the distal end of each of the elongate arms (52) is within said passageway (fig. 5), in order to provide adhesive pads that are releasably secured in place and may be readily replaced. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Taylor with the pivoting securing mechanisms of Fogarty in order to provide adhesive pads that are releasably secured in place and may be readily replaced.

Claims 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Taylor in view of Agnone (US 3754331). Taylor teaches all limitations of preceding dependent claims 1 and 5, but fails to disclose wherein the elongate member and pad form a ball and socket connection. Agnone teaches forceps wherein the distal pads connect to the elongate members by means of a ball and socket joint in order to allow the pads to move independently of the elongate arms and gain a better grip on the tissue. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Taylor with a ball and socket joint as taught by Agnone in order

to allow the pads to move independently of the elongate arms and gain a better grip on the tissue.

Claims 25 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Taylor as described previously, in view of Taylor. Taylor as described previously teaches all limitations of preceding dependent claim 22, but fails to explicitly teach wherein the connector is a rotatable snap fit connector that connects the adhesive pad to the tong to pivot at least about the longitudinal axis and an axis substantially perpendicular to the longitudinal axis. Taylor does however teach wherein it would be desirable to provide a ball and socket in order to permit the contact members to self-align and engagingly conform to the surface of the tissue. It would thus have been obvious to one of ordinary skill in the art at the time the invention was made to modify the apparatus of Taylor as previously described with a snap fit ball and socket joint in order to permit the contact members to self-align and engagingly conform to the surface of the tissue.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalie Pous whose telephone number is (571) 272-6140. The examiner can normally be reached on Monday-Friday 8:00am-5:30pm, off every 2nd Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NRP
4/23/07


ANH TUAN T. NGUYEN
SUPERVISORY PATENT EXAMINER
4/23/07